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5487	7590	02/13/2008		
ANDREA Q. RYAN			EXAMINER	
SANOFI-AVENTIS U.S. LLC			KOLKER, DANIEL E	
1041 ROUTE 202-206				
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BRIDGEWATER, NJ 08807			PAPER NUMBER	
			1649	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/691,079

Applicant(s)

MERCKEN ET AL.

Examiner

DANIEL KOLKER

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/3/07, 11/13/07.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 6, 7, 9 and 15 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1, 6, 7, 9 and 15 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

1. The remarks and amendments filed 3 October 2007 have been entered. Claims 1, 6 – 7, 9, and 15 are pending and under examination.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3 October 2007 has been entered.

Withdrawn Rejections and Objections

3. The following rejections and objections set forth in the previous office action are withdrawn:
 - A. The objection to claims 6, 7, and 9 is withdrawn in light of the amendments which recite more conventional claim language.
 - B. The rejection under 35 USC 112, second paragraph, is withdrawn in light of the amendments which provide proper antecedent basis and clarify the scope of the claims.
 - C. The rejections under 35 USC §§ 102 and 103 over Williamson are withdrawn in light of the amendments. The reference does not teach introducing APP into the cell as required by independent claim 1.

New Rejections and Objections

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6 – 7, 9, and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in

Art Unit: 1649

the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The examiner is unable to find support for step (d) of claim 1, specifically measuring the phosphorylation activity of Src protein in response to candidate compounds. While the specification as originally filed describes assays in which cells expressing Src and introduced APP are contacted with candidate compounds and the degree of A β and APP secretion were measured (see for example paragraph spanning pp. 9 – 10), the examiner is unable to find description of measuring *phosphorylation activity of Src* in such assays. Thus claim 1 recites new matter. Claims 6 – 7, 9, and 15 depend from claim 1 but are not limited to elements set forth in the originally-filed disclosure.

Claim 15 also recites the limitation “wherein said phosphorylation activity is the measurement of tyrosine phosphorylation of APP.” In the remarks filed 3 October 2007, applicant indicated that support for this limitation can be found at p. 7 lines 19 – 26. The examiner has closely studied this section of the specification. While this section presents a hypothesis that APP is phosphorylated by Src, this section is not part of the disclosure of screening assays that require presence of APP and Src. That description begins on p. 9. Additionally, the examiner is unable to find disclosure of measurement of phosphorylation of APP by Src. The cited paragraph on p. 7 merely presents a conclusion that APP is phosphorylated by Src but does not describe the step of measuring such phosphorylation.

Conclusion

5. No claim is allowed.
6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

A. Canet-Aviles et al. (15 June 2002. *Molecular Brain Research* 102:62-72). The reference teaches Src inhibitor PP1 inhibits muscarine-stimulated sAPP release by 70% (see p. 66 lines 2 - 4) and concludes the data that Src is several steps upstream of APP secretion (p. 70 Figure 6). However Canet-Aviles does not teach measuring the degree of APP phosphorylation by Src.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL KOLKER whose telephone number is (571)272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

Art Unit: 1649

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel E. Kolker, Ph.D./

Patent Examiner, Art Unit 1649

February 12, 2008